Treatment of Patients with Metastatic Melanoma Using Recombinant Vaccinia and Fowlpox Viruses Encoding the Tyrosinase Antigen in Combination with Interleukin-2

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Non-Technical Abstract:

This study is designed for the treatment of patients who have advanced metastatic melanoma. Patients will receive anti-melanoma vaccines made from two different but similar viruses, known as fowlpox (harmless to humans) and vaccinia (previously used to vaccinate people against smallpox). Each virus will carry the gene for tyrosinase, a protein commonly found in melanoma tumors. The viruses will act as vehicles to express the tyrosinase protein in vaccinated patients in such a way that the cells of the immune system may become activated against tyrosinase and hence against melanoma tumor cells. The viruses will be administered by intramuscular injection, and will be given in an alternating fashion designed to minimize immune responses against either virus by itself while maximizing immune responses against the tyrosinase protein. As part of this treatment, patients will also receive interleukin-2 (IL2) administered by vein in the hospital. IL2 is a substance found in the immune system, that may boost the immune response to the vaccines. It is also an active drug by itself for treating melanoma, and has been approved by the FDA for this indication. This study is designed to detect a clinical response rate in the treated patients that exceeds the historical response rate of 15% observed in melanoma patients treated with IL2 alone. Clinical response is defined as either a complete or partial disease remission. The secondary objective of this study is to obtain information on the immune responses against tyrosinase and melanoma tumor cells that may be generated as a result of treatment, using laboratory tests to measure responses in circulating blood cells and serum that will be collected from patients enrolled and treated on this study. The proposed study follows our previous clinical trial using the same vaccines to treat patients with metastatic melanoma, in which a number of tumor responses were observed and some laboratory evidence showing that the vaccines raised immunity against tyrosinase was generated. The current trial uses a different vaccination schedule and provides that all patients will receive IL2 with their vaccines, in an attempt to improve upon the previously observed results.